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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/722,737	11/25/2003	Bradley S. Galer	BSG 021 US	7300
35812	7590	09/10/2007		
GUY DONATIELLO ENDO PHARMACEUTICALS 100 Endo Boulevard CHADDS FORD, PA 19317			EXAMINER GEORGE, KONATA M	
			ART UNIT	PAPER NUMBER
			1616	
			MAIL DATE	DELIVERY MODE
			09/10/2007	PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

## Office Action Summary

Application No.

10/722,737

Applicant(s)

GALER, BRADLEY S.

Examiner

Konata M. George

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 23 March 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-11 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-11 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date <u>3/23/07</u> . | 6) <input type="checkbox"/> Other: _____  |

### **DETAILED ACTION**

Claims 1-11 are pending in this application.

#### ***Information Disclosure Statement***

1. The information disclosure statement (IDS) submitted on March 23, 2007 was noted and the submission is in compliance with the provisions of 37 CFR 1.97. Accordingly, the examiner has considered the information disclosure statement.

#### ***Action Summary***

2. The rejection of claims 1 and 11 under 35 U.S.C. 102(b) as being anticipated by Forrest as evidenced by Hawley's Condensed Chemical Dictionary is hereby withdrawn in view of applicants arguments.

3. The rejection of claims 1-11 under 35 U.S.C. 103(a) as being unpatentable over Katz et al. in view of Goodman and Gilman's (The Pharmacological Basis of Therapeutics) is being maintained for the reasons stated in the office action dated August 4, 2006.

#### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
  2. Ascertaining the differences between the prior art and the claims at issue.
  3. Resolving the level of ordinary skill in the pertinent art.
  4. Considering objective evidence present in the application indicating obviousness or nonobviousness.
4. Claims 1-11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Katz et al. (US 5,028,435) in view of Goodman and Gilman's (The Pharmacological Basis of Therapeutics).

Applicant claims a method for treating neuropathically-induced negative sensory phenomena comprising applying an anesthetic to a patient. The anesthetic can be a benzoic acid derivative such as lidocaine, cocaine, etc. and is delivery via a patch.

***Determination of the scope and content of the prior art***

**(MPEP §2141.01)**

Katz et al. disclose a system and method for delivery for transdermal drug delivery. The system comprises a matrix layer having a backing or enclosure, wherein the matrix layer contains a drug (col. 2, lines 58-60). Column 5, lines 43-55 teach exemplary drugs which may be delivered by the system of which anesthetics are disclosed (lines 44-45). Figure 1, discloses a system comprising a backing layer and a matrix layer containing the drug (as a solid or liquid) and polymeric beads (col. 11, lines

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55-65). Column 5, lines 23-34 teach that the matrix layer can be made from polyvinyl chlorides, silicon rubbers, etc.

***Ascertainment of the difference between the prior art and the claims***

**(MPEP §2141.02)**

Katz et al. do not teach the specific anesthetic as claimed by applicant or the weight percent of the drug in the patch. It is for this that Goodman and Gilman's is joined.

Goodman and Gilman's teach examples of local anesthetics such as lidocaine, dibucaine, etc. It is taught that lidocaine can be prepared as an ointment, jelly or topical solution (See Preparations, page 320). It is also taught that market preparations contain 0.5 to 20% and topical mucosal compositions 1 to 5%.

***Finding of prima facie obviousness***

***Rational and Motivation (MPEP §2142-2143)***

It would have been obvious to one of ordinary skill in the art at the time the invention was made to use the teachings of Goodman and Gilman's that lidocaine can be administered topically as an anesthetic in the system of Katz et al. which discloses a transdermal system which can comprise anesthetics to disclose the invention as claimed. Although it is not explicitly disclosed, administering the system near the locus of the negative sensory phenomena would be within the skill of the ordinary worker as

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part of the process of normal optimization to achieve the desired results of the claimed method.

### ***Response to Arguments***

5. Applicant's arguments filed March 23, 2007 have been fully considered but they are not persuasive.

Applicant has not responded to the 35 U.S.C. 103(a) rejection, therefore, it is being maintained for the reasons stated above.

### ***Conclusion***

6. Claims 1-11 are rejected.

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

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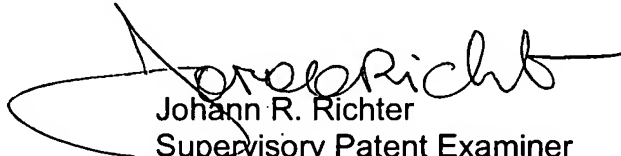
### ***Telephone Inquiries***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Konata M. George, whose telephone number is 571-272-0613. The examiner can normally be reached from 8:00AM to 6:30PM Monday to Thursday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Johann R. Richter, can be reached at 571-272-0646. The fax phone numbers for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have question on access to the Private Pair system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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